

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1. (Currently amended) A timed-release compression-coated solid composition for oral administration to a subject, said composition comprising:
 - a) a core tablet comprising a drug and a freely erodible filler, wherein the freely erodible filler is 1 or 2 or more selected from the group consisting of malic acid, citric acid, tartaric acid, polyethylene glycol **having a molecular weight of about 400 to 20,000**, sucrose, and lactulose, wherein said core tablet erodes approximately 40% to approximately 90% in the digestive tract of said subject, wherein said core tablet does not contain a hydrogel-forming polymer;
 - i) wherein said drug is metabolized by cytochrome P-450; or**
 - ii) wherein said drug inhibits metabolism by cytochrome P-450; or**
 - iii) wherein said drug is absorbed via a carrier on an epithelial cell of the small intestine;**
 - b) an outer layer, said outer layer is made from a hydrogel-forming polymer substance and a hydrophilic base, wherein said hydrogel-forming polymer substance is made from at least one type of polyethylene oxide **with a viscosity-average molecular weight of 2,000,000 or higher**, and said hydrophilic base is polyethylene glycol; and
 - c) wherein the outer layer does not contain the drug.
2. (Canceled)
3. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein there is approximately 75 wt% or less of said drug, approximately 5 to approximately 80 wt% freely erodible filler, approximately 10 to approximately 95 wt% hydrogel-forming polymer substance, and approximately 5 to approximately 80 wt% hydrophilic base.

4. (Canceled)

5. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the freely erodible filler is 1 or 2 or more selected from the group consisting of malic acid, citric acid and tartaric acid.

6. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the freely erodible filler for a basic drug is 1 or 2 or more selected from the group consisting of malic acid, citric acid and tartaric acid.

7. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the freely erodible filler for an acidic or neutral drug is 1 or 2 or more selected from the group consisting of polyethylene glycol, sucrose or lactulose.

8-12. (Canceled)

13. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the hydrogel-forming polymer substance is at least 1 type of polyethylene oxide and further contains red ferric oxide and/or yellow ferric oxide.

14. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein a drug is brought to be effectively released or absorbed in the lower digestive tract.

15. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein a drug is brought to be effective for chronopharmacotherapy.

16.-17 (Canceled)

18. (Currently amended) The timed-release compression-coated solid composition for oral administration according to claim 1 ~~[[16]]~~, wherein the drug is metabolized by CYP3A4.

19. (Currently amended) The timed-release compression-coated solid composition for oral administration according to claim 1 ~~[[17]]~~, wherein the drug has the effect of inhibiting metabolism by CYP3A4.

20. (Original) The timed-release compression-coated solid composition for oral administration according to claim 1, wherein the drug is 4'-[(2-methyl-1,4,5,6-tetrahydroimidazo[4,5-d][1]benzazepin-6-yl)carbonyl]-2-phenylbenzanilide or its salt.

21. (Currently amended) A method of timed-release of a drug, whereby the composition is orally administered, said composition comprising:

a) a core tablet comprising a drug and a freely erodible filler, wherein the freely erodible filler is 1 or 2 or more selected from the group consisting of malic acid, citric acid, tartaric acid, polyethylene glycol **having a molecular weight of about 400 to 20,000**, sucrose, and lactulose, wherein said core tablet erodes approximately 40% to approximately 90% in the digestive tract of said subject, wherein said core tablet does not contain a hydrogel-forming polymer;

i) wherein said drug is metabolized by cytochrome P-450; or

ii) wherein said drug inhibits metabolism by cytochrome P-450; or

iii) wherein said drug is absorbed via a carrier on an epithelial cell of the small intestine;

b) an outer layer, said outer layer is made from a hydrogel-forming polymer substance and a hydrophilic base, wherein said hydrogel-forming polymer substance is made from at least one type of polyethylene oxide **with a viscosity-average molecular weight of 2,000,000 or higher**, and said hydrophilic base is polyethylene glycol; and

c) wherein the outer layer does not contain the drug, thereby time releasing the drug.

22. (Canceled)

23. (Canceled)

24. (Original) In a hydrogel-forming compression-coated solid pharmaceutical preparation comprising: a core tablet containing drug and outer layer made from hydrogel-forming polymer substance and hydrophilic base, the improvement which comprises a timed-release compression-coated solid composition according to claim 1.

25. (Currently amended) A hydrogel-forming compression-coated solid pharmaceutical preparation comprising:

a core tablet containing drug and outer layer made from hydrogel-forming polymer substance and hydrophilic base, the improvement which comprises a timed-release compression-coated solid composition for oral administration, said composition comprising:

(1) a drug and freely erodible filler wherein the freely erodible filler is 1 or 2 or more selected from the group consisting of malic acid, citric acid, tartaric acid, polyethylene glycol having a molecular weight of about 400 to 20,000, sucrose, and lactulose, are mixed with the core tablet, wherein said core tablet does not contain a hydrogel-forming polymer;

a) wherein said drug is metabolized by cytochrome P-450; or

b) wherein said drug inhibits metabolism by cytochrome P-450; or

c) wherein said drug is absorbed via a carrier on an epithelial cell of the small intestine;

(2) the percentage erosion of the core tablet is approximately 40 to approximately 90%; and

(3) the outer layer does not contain the drug and wherein said outer layer is made from at least one type of polyethylene oxide **with a viscosity-average molecular weight of 2,000,000 or higher**, and polyethylene glycol.

26. (Original) The timed-release compression-coated solid composition for oral administration according to claim 25, wherein the drug is 4'-[(2-methyl-1,4,5,6-tetrahydroimidazo[4,5-d][1]benzazepin-6-yl)carbonyl]-2-phenylbenzanilide or its salt.

27. (Currently amended) A timed-release compression-coated solid composition for oral administration, to a subject, said composition comprising:

a) a core tablet comprising a drug and a freely erodible filler, wherein the freely erodible filler is 1 or 2 or more selected from the group consisting of malic acid, citric acid, tartaric acid, polyethylene glycol **having a molecular weight of about 400 to 20,000**, sucrose, and lactulose, wherein said core tablet does not contain a hydrogel-forming polymer, and wherein said core tablet erodes approximately 40% to approximately 90% in the digestive tract of said subject, wherein percentage erosion is determined by a method **wherein said drug is metabolized by cytochrome P-450; or wherein said drug inhibits metabolism by cytochrome P-450; or wherein said drug is absorbed via a carrier on an epithelial cell of the small intestine**:

i) a compression-coated tablet is moistened for 3 hours in water at 37° C;

ii) the gelled part of the tablet is peeled off and the portion of the core tablet that has not eroded is removed;

iii) the core tablet is allowed to dry overnight in a dryer at 40° C and the weight is determined;

iv) the value obtained by subtracting dry weight from initial core tablet weight is multiplied by 100;

b) an outer layer, said outer layer is made from a hydrogel-forming polymer substance, and a hydrophilic base, wherein said hydrogel-forming polymer substance is made

from at least one type of polyethylene oxide with a viscosity-average molecular weight of 2,000,000 or higher, and said hydrophilic base is polyethylene glycol; and

c) wherein the outer layer does not contain the drug.

28. (Previously presented) The method of claim 21, wherein interaction is reduced between the drug and a concomitantly used second drug, wherein both drugs employ the same routes for drug absorption.

29. (Previously presented) The method of claim 28, wherein the drug inhibits drug metabolism *in vivo* in humans of the second drug.

30. (Currently amended) A timed-release compression-coated solid composition for oral administration to a subject, said composition comprising:

a) a core tablet comprising a drug and a freely erodible filler, wherein the freely erodible filler is 1 or 2 or more selected from the group consisting of malic acid, citric acid, tartaric acid, polyethylene glycol having a molecular weight of about 400 to 20,000, sucrose, and lactulose, wherein said core tablet erodes approximately 40% to approximately 90% in the digestive tract of said subject, wherein said core tablet contains about 10% to about 50% w/w of a hydrogel-forming polymer;

i) wherein said drug is metabolized by cytochrome P-450; or

ii) wherein said drug inhibits metabolism by cytochrome P-450; or

iii) wherein said drug is absorbed via a carrier on an epithelial cell of the small intestine;

b) an outer layer, said outer layer is made from a hydrogel-forming polymer substance and a hydrophilic base, wherein said hydrogel-forming polymer substance is made from at least one type of polyethylene oxide with a viscosity-average molecular weight of 2,000,000 or higher, and said hydrophilic base is polyethylene glycol; and

c) wherein the outer layer does not contain the drug.

31. (Previously presented) The timed-release compression-coated solid composition for oral administration according to claim 30, wherein the freely erodible filler is 1 or 2 or more selected from the group consisting of malic acid, citric acid and tartaric acid.

32. (Previously presented) The timed-release compression-coated solid composition for oral administration according to claim 30, wherein the freely erodible filler for a basic drug is 1 or 2 or more selected from the group consisting of malic acid, citric acid and tartaric acid.

33. (Previously presented) The timed-release compression-coated solid composition for oral administration according to claim 30, wherein the freely erodible filler for an acidic or neutral drug is 1 or 2 or more selected from the group consisting of polyethylene glycol, sucrose or lactulose.

34. (Previously presented) The timed-release compression-coated solid composition for oral administration according to claim 30, wherein the hydrogel-forming polymer substance is at least 1 type of polyethylene oxide and further contains red ferric oxide and/or yellow ferric oxide.

35. (Previously presented) The timed-release compression-coated solid composition for oral administration according to claim 30, wherein a drug is brought to be effectively released or absorbed in the lower digestive tract.

36. (Previously presented) The timed-release compression-coated solid composition for oral administration according to claim 30, wherein a drug is brought to be effective for chronopharmacotherapy.